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10/606,229

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Manfred Bohn

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

SCHLIENTZ, LEAH H

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

MAILED

Application Number: 10/606,229
Filing Date: June 26, 2003
Appellant(s): BOHN ET AL.

DEC 13 2007
GROUP 1600

Thalia V. Warnement
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/15/2007 appealing from the Office action mailed 12/15/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The Board is informed of the Board's prior decision in Appeal No. 2004-0309 (in parent application 09/077,194), mailed September 15, 2004, a copy of which is contained in the brief. Also, Appellants filed a Notice of Appeal in application no. 09/077,194 on July 24, 2007.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,185,106	DITTMAR	1-1980
5,834,409	RAMACHANDRAN	11-1998

Hanel et al., *Mycoses*, 34 (Supp 1), 1991, p. 91-93 (abstract only).

Online Medical dictionary (27 Sep 1997)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14 – 23 and 26 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dittmar *et al.* (US 4,185,106) in view of Hanel *et al.* (*Mycoses*, 34 (Supp 1), 1991, p. 91-93 (abstract only)) and Online Medical Dictionary or Ramachandran *et al.* (US 5,834,409).

The claims are drawn to a method of treating seborrheic dermatitis in a human patient using a single composition comprising a sole active agent consisting of at least one 1-hydroxy-2-pyridone of general formula I as recited in claim 14, and at least one surfactant, wherein the composition has a pH ranging from about 4.5 to about 6.5.

Dittmar (US '106) teaches an effective anti-dandruff treatment using a pharmaceutical composition containing 1-hydroxy-pyridones (e.g. ciclopirox (1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) or octopirox (1-hydroxy-4-methyl-6-(2,4,4-trimethyl-pentyl)-2-pyridone) as active agent, see abstract and column 2.

Applicant's claims differ because they are directed to a method of treating seborrheic dermatitis.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to extend the teachings to include seborrheic dermatitis when Dittmar (US '106) is taken in view of Hanel (1991) and Online Medical Dictionary or US 5,834,409 because the latter references remedy the deficiency of Dittmar's teaching.

Firstly, Hanel *et al.* (1991) teach that antimycotic agents ciclopiroxamine (i.e. cic, or 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone) or rilopirox are effectively used to treat seborrheic eczema in human patients, see abstract.

It is noted that seborrheic eczema is an alternative term for seborrheic dermatitis (see definition of Online Medical Dictionary).

Hanel further teaches the significant therapeutic effectiveness achieved by ciclopirox (cic, hereafter) where strong inhibition of inflammation and infiltration and flakiness has been obtained by cic treatment in the form of a cream in human patients. Thus, the deficiency of Dittmar is well-remedied and it would have been obvious to one of ordinary skill in the art to select a composition containing 1-hydroxy-2-pyridones (e.g. cic or rilopirox) as a drug of choice and a surfactant to treat seborrheic dermatitis effectively because the safety and therapeutic efficacy are well proven by the references and the increased selection option increases industrial applicability where the main drawback factors associated with manufacturing antimycotic, antifungal and antibacterial pharmaceutical products are resolved since the toxicities and safety are well proven by the cited references in addition to cost reduction (by avoidance of toxicity, efficacy studies) could benefit the users (patients).

All other critical elements (e.g. surfactant, pH, etc.) required by the instant claims are well taught in the primary Dittmar reference. For example, Dittmar indirectly teaches weakly acidic composition which is the desirable pH for hair composition (see column 9, lines 28-29). Weakly acidic pH (pH around 4.5-6.5) is most desirable / suitable pH range for hair products, also well recognized in the pharmaceutical / cosmetic industries (see PTO-892 for supporting documents for pH selection commonly practiced in the industries US 3,987,161; US 3,996,146; US 5,761,824; US 5,834,409). Thus, the claimed subject matter is not patentably distinct over the teaching of the prior art of record. One would have been motivated to combine the references and make the modification because they are drawn to the same technical field (constituted with the same ingredients), share common utilities, and are pertinent to the problem with which applicant is concerned. MPEP 2141.01(a).

(10) Response to Argument

Appellants' arguments have been fully considered but they are deemed unpersuasive. More specifically, Appellants argue on pages 10 – 15 of the Appeal Brief that the claims on appeal are directed to a method of treating *seborrheic dermatitis* (SD) comprising an effective amount of the 1-hydroxy-2-pyridone compounds recited in the claims, and that in contrast the primary reference relied upon, Dittmar, relates to treating *dandruff* with 1-hydroxy-2-pyridones. Appellants contend that SD and dandruff are two entirely different conditions, and that a reference using 1-hydroxy-2-pyridones to treat dandruff does not make obvious a method of treating a different disorder, i.e. SD.

Appellants argue that the examiner acknowledges that Dittmar does not teach a method of treating SD, and relies on Hanel, which discusses the treatment of seborrheic eczema (i.e. which is defined as equivalent to seborrheic dermatitis via an on-line medical dictionary) to remedy the shortcomings of Dittmar. Appellants argue that there is no nexus between Dittmar's treatment of dandruff and Hanel's treatment of seborrheic eczema. Appellants cite the decision in the KSR case, and argue that "the examiner's alleged reasoning is based on generalities of "same technical fields" and "sharing common utilities" do not speak to the specific teachings of the references invoked by the examiner. Applicant argues that "as for the Examiner's suggestion that Dittmar and Hanel use the "same ingredients," the Hanel abstract does not provide a complete description of the composition used in order to allow a useful comparison between the ingredients in Dittmar's composition and the ingredients in Hanel's composition."

It is the position of the examiner that one of ordinary skill in the art would have recognized that both Dittmar and Hanel teach the use of the same compound (i.e. ciclopiroxolamine) which may be used to treat similar conditions (i.e. dandruff, as in Dittmar, or seborrheic eczema (dermatitis), as in Hanel). Accordingly, the nexus between the Dittmar and Hanel references relied upon by the examiner for rejection of the pending claims is the compound, ciclopiroxolamine. For example, the Hanel reference accomplishes the claimed method (i.e. a method of treating of seborrheic dermatitis), and does so via application of a cream comprising ciclopiroxolamine. While the Hanel reference is silent with regard to the surfactant components and pH of the

cream, such components of a cream or similar composition are well shown in the art to be known for the successful formulation of ciclopiroxolamine and related compounds in various shampoos, creams, etc, for use in a similar condition occurring on the scalp, as in Dittmar. As such, one of ordinary skill in the art would have been motivated to utilize known formulations of ciclopiroxolamine (i.e. those including a surfactant and weakly acidic pH, for example, as taught by Dittmar) which would provide benefits of reduced manufacturing uncertainties, cost reduction, resolved toxicity and safety studies, etc. as set forth in the Office Action mailed 12/15/2006.

Appellants further argue on pages 15 – 16 of the Appeal Brief that Dittmar teaches the treatment of dandruff, and that appellants have maintained throughout prosecution the position that dandruff and SD are two different conditions. Appellants cite the declaration of Dr. Michael Wortzman, filed September 7, 2006, which recites that dandruff is a “noninflammatory scaling of the scalp” and “seborrheic dermatitis is an “inflammatory, erythematous and scaling eruption,” and that “the scales of dandruff look different from the scales of seborrheic dermatitis.” Appellants argue that because dandruff and seborrheic eczema are different conditions, the skilled artisan would not have been motivated to modify or combine the teachings of Dittmar relating to dandruff with the teachings of Hanel relating to seborrheic eczema, and that the alleged teachings of the “medical dictionary” that SD and seborrheic eczema are equivalent are irrelevant to linking the teaching of Dittmar to the teaching of Hanel.

It is the position of the examiner that while the declaration of Dr. Wortzman has been fully considered, and it is acknowledged that dandruff and seborrheic dermatitis (eczema) are distinct conditions, one of ordinary skill in the art would have recognized that compositions comprising the same compound (i.e. ciclopiroxolamine) were used in the Dittmar and Hanel references to treat conditions which are at least similar and related (i.e. dandruff and SD). The declaration of Dr. Wortzman, at page 2, recites that "one of ordinary skill in the art would not find it obvious to use a certain composition to treat SD, merely because the same composition is used to treat dandruff." This is found non-persuasive because the document provided as Appendix C with the declaration specifically states that "dandruff, seborrheic dermatitis and psoriasis are described as chronic, scaly dermatoses. They may be placed on a spectrum ranging from dandruff, a minor problem.... to psoriasis, a clinical condition that can have significant physical, psychologic and economic consequences." The document provided as Appendix C further teaches that "many cases of seborrheic dermatitis will respond to the same non-prescription drug regimen used to treat dandruff" (page 550).

Appellants further argue on pages 16 – 18 of the Appeal Brief that the examiner acknowledges the non-obviousness of independent claims 14, 19 and 26. Appellants rely upon the declaration of Mr. Kriel, which discusses the commercial success of Loprox® Shampoo. Appellants contend that the Loprox® Shampoo and Stieprox® Shampoo are commercially successful, and that "both products contain the claimed active ingredients and various different combinations of surfactants, all of which are

encompassed in the scope of the claims, showing that the commercial success is actually commensurate in scope with the claims.”

It is the position of the examiner while allowable subject matter was indicated at one point during prosecution, upon further consideration of the declaration and in view of newly found art (i.e. the Hanel reference), the claims were indeed found to be unpatentable. As stated above, the Hanel reference accomplishes the claimed method (i.e. treatment of seborrheic dermatitis (eczema) using a cream comprising ciclopiroxolamine). While the Hanel reference is silent with regard to the surfactant components and pH of the cream, such components of a cream or similar composition are well shown in the art to be known for the successful formulation of ciclopiroxolamine and related compounds in various shampoos, creams, etc, for use in treating a similar condition occurring on the scalp, as in Dittmar.

Regarding the declaration of Mr. Kriel, it is the position of the examiner that the reference to the cited product (Loprox® Shampoo) is not commensurate in scope with the claims. Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. *In re Tiffin*, 448 F.2d 791, 171 USPQ 294 (CCPA 1971) (evidence showing commercial success of thermoplastic foam “cups” used in vending machines was not commensurate in scope with claims directed to thermoplastic foam “containers” broadly). MPEP 716.03.

In the instant case, the Loprox® Shampoo product contains a single antifungal agent, ciclopiroxolamine, and includes sodium laureth sulfate, disodium laureth sulfosuccinate, sodium chloride USP and laureth-2 surfactants, according to Exhibit B

filed with the declaration of Mr. Kriel on 4/16/2007. However, the claims are drawn to a broad genus of compounds and surfactants. The genus of compounds may be representative of thousands of potential antifungal compounds represented by generic formula I, as well as a broad genus of surfactants to be encompassed by any "anionic, cationic, nonionic or amphoteric" surfactants. Accordingly, the claimed composition is broader than the single product which has been alleged to have commercial success.

In addition, In considering evidence of commercial success, care should be taken to determine that the commercial success alleged is directly derived from the invention claimed, in a marketplace where the consumer is free to choose on the basis of objective principles, and that such success is not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention, etc. *In re Mageli*, 470 F.2d 1380, 176 USPQ 305 (CCPA 1973) (conclusory statements or opinions that increased sales were due to the merits of the invention are entitled to little weight); *In re Noznick*, 478 F.2d 1260, 178 USPQ 43 (CCPA 1973).

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness. Accordingly, the 35 U.S.C. § 103(a) rejection has been maintained.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

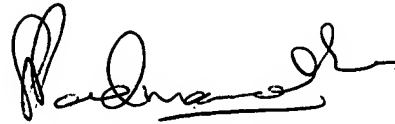
Michael Hartley
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1618



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER

Conferees:

Sreeni Padmanabhan



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Leah Schlientz

